U.S. Department of Labor

Employee Benefits Security Administration
Washington, D.C. 20210

SEP 28 2018

Austin R. Evers
American Oversight
1030 15th Street NW
Suite 8255
Washington, DC 20005

Dear Mr. Evers:

This letter is in response to your Freedom of Information Act (FOIA) request number ***F2017-844497*** addressed to the U.S. Department of Labor (DOL). Your requests were assigned to the Employee Benefits Security Administration (EBSA) for response. You requested the following: All responsive records from January 20, 2017, through the date the search is conducted.

F2017-844497:

1. All communications with any plaintiff in any of the 74 plaintiffs in the 13 federal cases concerning contraception coverage who have reported to settle or resolve legal actions against DOL that:
    a. request the federal government compensate the plaintiff for attorneys fee and costs or
    b. provide any support to justify any request for fees and costs, including any information regarding the amount of fees and costs incurred or the legal basis upon which the federal government might be obligated to cover a plaintiff's fees and costs.
2. Records sufficient to identify the amount and source of any funds paid or scheduled to be paid to plaintiffs to compensate them for costs and fees as part of the settlement of cases responsive to Item 1.
3. All emails sent to or received from an address not ending in .gov discussing, regarding, or relating to the Interim Final Rule regarding Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (ACA).
4. All emails sent to or received from an address not ending in .gov discussing, regarding, or relating to the Interim Final Rule regarding Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA.

The EBSA has completed its search in the National Office and no records were found responsive to your request for items numbers 1 and 2. The Office of the Solicitor Pension Benefits Security Division (PBSD) may have records responsive to these items. PBSD will respond directly to you.

For items numbers 3 and 4 we have located approximately 20 records/pages responsive to your request. These records are enclosed herewith and have been redacted to effect Exemption 6. Exemption 6 (5 U.S.C. 522(b)(6)) permits the withholding of information that would constitute an invasion of personal privacy.

If you would like to discuss any aspect of your request please do not hesitate to contact EBSA's FOIA Coordinator, Kathy Hoover at *hoover.kathy@dol.gov* or the DOL FOIA Public Liaison, Thomas Hicks, at 202-693-5427 or by email at *hicks.thomas@dol.gov*. Alternatively, you may contact the Office of Government Information Services (OGIS) within the National Archives and Records Administration (NARA) to inquire about the mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740-6001. You can also reach that office by e-mail at *ogis@nara.gov*, by phone at 202-741-5770, by fax at 202-741-5769, or by calling toll-free at 1-877-684-6448.

You may administratively appeal by writing to the Solicitor of Labor within 90 days from the date of this letter if you are not satisfied with the response to this request. The appeal must state in writing the grounds for the appeal, and it may include any supporting statements or arguments, but such statements are not required. In order to facilitate processing of the appeal, please include your mailing address and daytime telephone number, as well as a copy of the initial request and copy of this letter. The envelope and letter of the appeal should be clearly marked "Freedom of Information Act Appeal." Any amendment to the appeal must be made in writing and received prior to a decision. The appeal should be addressed to the Solicitor of Labor, Division of Management and Administrative Legal Services, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N2420, Washington, DC 20210. Appeals may also be submitted by email to *foiaappeal@dol.gov*. Appeals submitted to any other email address will not be accepted.

Sincerely,

Mark B. Connor
Director, Office of Outreach, Education and Assistance

From: Rivers, Amber - EBSA
To: Rhonda Reed
Sent: 11/15/2017 3:52:50 PM
Subject: RE: New Coverage for Preventive Services - Accommodation rule

Hi Rhonda – no worries at all. I just tried your office and left a message with your secretary. Feel free to give me a call at your convenience or we can set up a time to talk. Hope you are having a great day.

From: Rhonda Reed [mailto: Ex (6)
Sent: Thursday, November 02, 2017 2:16 PM
To: Rivers, Amber - EBSA
Subject: Re: New Coverage for Preventive Services - Accommodation rule

Hi Amber

I am so so sorry for the extremely late response. I was out of town on personal business so I was not checking email. I am available and will make myself available to talk when you have the time.

Thank you

On Tue, Oct 17, 2017 at 10:25 AM, Rivers, Amber - EBSA Ex (6) wrote:
Hi Rhonda – hope all is well. I'd be happy to discuss your questions. Do you have availability this week to chat? Thanks and my apologies on the delayed response!

Best,

Amber

From: Rhonda Reed [mailto Ex (6)
Sent: Wednesday, October 11, 2017 4:22 PM
To: Rivers, Amber - EBSA
Subject: New Coverage for Preventive Services - Accommodation rule

Hi Amber,

This Rhonda Reed with SPBA. Its been a while since we last talked. SPBA is an association for third party administrators (TPA) that administer benefits for self-funded (also called self-insured) plans.

The Religious Exemptions and Accommodations for Coverage of Certain Preventive Services rule states that this is for health insurance insurers and plans only. Is this correct?

Does this rule not apply to for self-funded (also called self-insured) plans?

Where there ever regulations or guidance that changed the previous interim final rules that stated TPAs must pay for contraceptive services that church plans, eligible organizations, closely held for profit plans do not want to pay for?

The last rules I have seen left TPAs on the hook for for self-funded (also called self-insured) plans that did not want to cover contraceptive services

Thank you for the clarification

--

Rhonda Reed
Regulatory and Legislative Analyst
Society of Professional Benefit Administrators
Two Wisconsin Circle
Suite 670
Chevy Chase, Maryland 20815

Ex (6)

The contents of this email are intended to convey general information only and not to provide legal advice or opinions. The contents of this email should not be construed as, and should not be relied upon for, legal or tax advice in any particular circumstance or fact situation. An attorney should be contacted for advice on specific legal issues.

--

Rhonda Reed
Regulatory and Legislative Analyst
Society of Professional Benefit Administrators
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Suite 670
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From: Rivers, Amber - EBSA
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Rhonda Reed
Regulatory and Legislative Analyst
Society of Professional Benefit Administrators
Ex (6)

From: Rhonda Reed
To: Rivers, Amber - EBSA
Sent: 12/7/2017 2:48:55 PM
Subject: Re: New Coverage for Preventive Services - Accommodation rule

Hi Amber.

I have been on leave and am returning. Hope all is well. I see I missed your call, my apologies. I still need guidance to my question please. When you have time I am available to talk. My number is Ex (6)

Thank you so very much

On Wed, Nov 15, 2017 at 3:52 PM, Rivers, Amber - EBSA <Ex (6)> wrote:

Hi Rhonda – no worries at all. I just tried your office and left a message with your secretary. Feel free to give me a call at your convenience or we can set up a time to talk. Hope you are having a great day.

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Rhonda Reed

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--

Rhonda Reed
Regulatory and Legislative Analyst
Society of Professional Benefit Administrators
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From:	Ramsay, Rick
To:	CMS CCIIO Office of the Director; Pate, Randy (CMS/CCIIO); Hammer, Christine E. (CMS/CCIIO); Mayhew, James A. (CMS/CCIIO); Carver, Katherine J. (CMS/CCIIO); Clemmons, Cam L. (CMS/CCIIO); Mlawsky, David (CMS/CCIIO); Turner, Amy - EBSA; Rivers, Amber - EBSA; Kevin.Knopf(Ex. (6) Kathryn.Johnson(Ex. (6) Carol.Weiser(Ex. (6) Wilkinson, Emily (HHS/IOS); Wilkinson, Emily (CMS/CCIIO); Brady, Will (HHS/IOS); Wilder, Thomas J
Sent:	11/27/2017 9:13:38 AM
Subject:	Preventive Services Discussion - UHG- Follow-up Material
Attachments:	Preventive Services Tri-Agency Follow-up.pdf

Good morning. As a follow-up to our recent discussion regarding preventive services, we want to thank you for your time and the robust discussion. Attached you will find additional recommendations regarding improving the process for improving the process for covering preventive services.

We look forward to a continued dialogue to share our thoughts on policy recommendations the Agencies can undertake to improve the healthcare experience and healthcare outcomes for consumers. UnitedHealthcare is dedicated to helping people live healthier lives and making our nation's health care system work better for everyone. We serve the health care needs of more than 100 million people worldwide, funding and arranging health care on behalf of individuals, employers and the government. As America's most diversified health and well-being company, we not only serve many of the country's most respected employers, but we are also the nation's largest Medicare health plan – serving nearly one in five seniors nationwide – and one of the largest Medicaid health plans, supporting underserved communities in 24 states and the District of Columbia. Recognized as America's most innovative company in our industry by Fortune magazine for six years in a row, we bring innovative health care solutions to scale to help create a modern health care system that is more accessible, affordable, and personalized for all Americans.

Rick

Rick Ramsay
Vice President, Healthcare Policy & Reform Implementation
UnitedHealthcare Employer & Individual

Ex (6)

Improving the Process for Covering Preventive Services

Health plans provide coverage for preventive services without cost-sharing by the patient. This approach gives patients access to evidence-based clinical preventive health services and helps to promote increased use of preventive care.

Plans must cover services recommended by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices, and Health Resources and Services Administration. Coverage generally begins one year after the date a recommendation or guideline for preventive services is released by one of the advisory groups. There are several improvements that can be made to this process to streamline the integration of preventive services into health coverage and the healthcare delivery system.

Allow Public Comment When Recommendations/Guidelines are Issued

The advisory groups examine preventive services from a clinical perspective to determine if a particular service, immunization or drug will improve population health by either preventing a disease (e.g., a vaccination preventing an infection) or promoting early detection of a condition that is associated with improved outcomes (e.g., cancer screenings). Health plans must then turn those clinical practice recommendations into benefit coverage parameters by applying reasonable medical management criteria. Once the recommendations are announced by one or more of the advisory groups, questions may arise with respect to coverage for specific services or drugs used to address the condition (e.g., what cost effective treatments should be covered, for whom, at what frequency, and which clinical integral services are required even though they are not explicitly included in the guidance?). To date, the federal agencies that regulate health plans have issued numerous "frequently asked questions" guidance documents discussing various issues regarding coverage for preventive services. These guidance materials have addressed a broad range of issues including tobacco cessation programs, lactation services, coverage for dependent children, breast cancer screening, and coverage of out-of-network providers.

Health plans, health care providers, patient advocates, and other stakeholders should be given an opportunity to review and provide comments on coverage issues after clinical recommendations are released by an advisory committee. Providing a 30 day comment period will allow full consideration and input on the advisory committee recommendations and discussion of how best to cover and support implementation in the healthcare delivery system. Federal agencies should then take 30 days after the comment deadline to finalize the preventive services recommendation and provide any guidance on coverage questions.

Give Health Plans Time to Implement Preventive Service Recommendations

As discussed, the one-year implementation timeline may be shortened when federal regulatory agencies issue guidance clarifying how preventive services must be covered. In some cases health plans are expected to immediately implement the new requirements or were provided a short timeframe to comply. For example, health plans were given 60 days to cover pre-screening consultations in connection with a colonoscopy.[1]

[1] *FAQs About Affordable Care Act Implementation (Part XXIX)*, FAQ 7.

Adopting new coverage requirements may involve significant changes to administrative and operational systems, information technology updates, changes to health care provider contracts, employer health plan and individual insurance policy modifications, and other implementation activities. Health plans should be given 12 months after the federal agencies finalize the advisory committee recommendations (and any additional guidance) to adopt the new requirements.

Recognize Evidence-Based Medical Management

Health plans are allowed to determine the frequency, method, treatment or care setting for preventive services based on evidence-based medical management techniques. However, the federal agencies have in some cases restricted the ability of health plans to exercise this judgment. For example, health plans must accept without question a treating health care provider's decision regarding coverage for specific contraceptive items or services, regardless of whether that decision is based on sound clinical evidence.[2]

Taking into consideration the opinion of an attending health care provider is an important component of any medical management process. However, health plans look at a broad range of concerns when determining how best to cover medical services including nationally recognized practice guidelines, clinical evidence and studies, and the overall cost and comparative efficacy of particular services that may not be readily available to the provider. The federal agencies should place the primary focus on the health plan's medical management process and support those evidence-based determinations.

[2] *FAQs About Affordable Care Act Implementation (Part XXVI)*, FAQs 2, 3, and 4.

From:	Rachel Gandell Tetlow
To:	Rivers, Amber - EBSA; Litton, Matthew - EBSA; Turner, Amy - EBSA
CC:	Contact - WB; OFCCP-Public
Sent:	10/6/2017 4:17:03 PM
Subject:	Women's Health Providers Request Withdrawal of IFRs
Attachments:	AAFP AAP ACP ACOG AOA APA Letter to President_Contraception IFRs.pdf; ACNM ACOG Letter to President.pdf

Good afternoon,

I wanted to be sure you had a copy of the attached letters requesting the immediate withdrawal of the two interim final rules released today that will restrict access to contraception:

A letter to President Trump signed by the American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians, American Congress of Obstetricians and Gynecologists, American Osteopathic Association, and the American Psychiatric Association.

A letter to President Trump signed by the American College of Nurse-Midwives and the American Congress of Obstetricians and Gynecologists.

Thank you for your review and consideration.

Sincerely

Rachel

Rachel Gandell Tetlow
Director, Federal Affairs
American Congress of Obstetricians and Gynecologists

Ex (6)

October 6, 2017

President Donald J. Trump
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Trump,

Our organizations, which represent more than 560,000 physicians and medical students, urge you to preserve guaranteed coverage of women's preventive services, including contraception, at no out-of-pocket cost in private insurance plans, and immediately withdraw the interim final rules titled "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act" and "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act." No woman should lose the coverage she has today.

Section 2713 of the Patient Protection and Affordable Care Act (ACA) requires all non-grandfathered individual and group health plans to offer coverage with no cost sharing of women's preventive services. Over 62 million women with private insurance now have access to these vital health care services, including breast and cervical cancer screening, breastfeeding services and supplies, contraception and contraceptive counseling. Coverage guidelines were developed based on the best clinical and scientific evidence, and contraception is a key piece of this comprehensive women's preventive services package. Maintaining access to this existing coverage is critical to ensuring American women and families can access the care that they need.

Contraception is an integral part of preventive care and a medical necessity for women during approximately 30 years of their lives. Access to no-copay contraception leads to healthier women and families. Any move to decrease access to these vital services would have damaging effects on public health. We know that when women have unplanned pregnancies, they are more likely to delay prenatal care, resulting in a higher risk of birth defects, low birth weight, and poor mental and physical function in early childhood.[i] No-copay coverage of contraception has improved the health of women and families and contributed to a dramatic decline in the unplanned pregnancy rate in the United States, including among teens, now at a 30-year low.[ii]

These rules will negatively impact access for women nationwide, and will negatively impact our economy. No-copay coverage of contraception saves money for taxpayers and state and federal governments. Unplanned pregnancies cost approximately $21 billion in government expenditures in 2008.[iii] Before the ACA, women were spending between 30% and 44% of their total out-of-pocket health costs just on birth control.[iv] After the ACA, women saved approximately $1.4 billion on out-of-pocket costs for contraception in one year.[v]

Changes to our healthcare system come with very high stakes – impacting tens of millions of our patients. Access to contraception allows women to achieve, lead and reach their full potentials, becoming key drivers of our Nation's economic success. These rules would create a new standard whereby employers can deny their employees coverage, based on their own moral objections. This interferes in the personal health care decisions of our patients, and inappropriately inserts a patient's employer into the physician-patient relationship. In addition, these rules open the door to moral exemptions for other essential

physician-recommended preventive services, such as immunizations. We urge you to immediately withdraw these harmful rules and instead partner with us to improve access to care for our patients.

Sincerely,

American Academy of Family Physicians

American Academy of Pediatrics

American College of Physicians

American Congress of Obstetricians and Gynecologists

American Osteopathic Association

American Psychiatric Association

Cc: The Honorable Jeff Sessions, Attorney General

The Honorable Don Wright, MD, MPH, Acting Secretary of HHS

The Honorable Steven Mnuchin, Secretary of the Treasury

The Honorable Alex Acosta, Secretary of Labor

---

[i] Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809–23. [PubMed] [Full Text]

[ii] Finer, L.B., Zolna, M.R. Declines in Unintended Pregnancy in the United States, 2008-2011. N Engl J Med 2016; 374:843-52.

[iii] Sonfield, A., Kost, K. Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010. New York: Guttmacher Institute, 2015. *Available at*: https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf

[iv] Access to contraception. Committee Opinion No. 615. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015;125:250–5..

[v] Health Reform: Implications for Women's Access to Coverage and Care. Issue Brief #7987-03. Kaiser Family Foundation. August 2013, *available at* https://kaiserfamilyfoundation.files.wordpress.com/2012/03/7987-03-health-reform-implications-for-women_s-access-to-coverage-and-care.pdf.

AMERICAN COLLEGE of NURSE-MIDWIVES
With women, for a lifetime®

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

October 6, 2017

The President
The White House
Washington, DC 20500

Dear Mr. President:

Representing professional societies in medicine and midwifery with scientific and clinical missions to protect and advance women's health, we write to express our deep disappointment that the Administration has today published two rules that will severely damage women's access to contraception, draw employers into the personal health choices and decisions of their female employees, impair the family planning choices of countless numbers of Americans, and turn back the clock on women's health.

Because these rules single out women for specific and targeted reduction of their access to care, and advances policy likely to increase health care costs overall, we respectfully request that the Administration withdraw these harmful rules and reinstate previous policy.

Section 2713(a)(4) of the Patient Protection and Affordable Care Act (ACA) requires non-grandfathered individual and group health plans to offer coverage with no cost sharing beyond premium payments of women's preventive services, as determined by the Health Resources and Services Administration (HRSA). Coverage guidelines are developed based on the best clinical and scientific evidence, and contraception is a key piece of this comprehensive women's preventive services package.

More than 62 million women gained access to coverage of preventive services, including contraception, with no cost sharing beyond premium payments,[i] resulting in $1.4 billion savings in out-of-pocket costs in one year.[ii] Before this coverage was available, women spent between 30% and 44% of their total out-of-pocket health costs just on birth control.[iii]

This coverage has contributed to our Nation's 30-year low in its unintended pregnancy rate, and the lowest teen pregnancy rate in recorded history.[iv] Increased access to contraception with no cost sharing also reduces abortion rates and enables women to attain education and employment goals that benefit our Nation's economic growth.[v] Births resulting from unintended or closely spaced pregnancies are associated with adverse maternal and child health outcomes, including delayed prenatal care, premature birth, and negative physical and mental health effects for children.[vi, vii, viii]

A full array of family planning services is vital for the health and well-being of women, their families, and our communities. The July 2015 accommodation rule sufficiently protects religious-based entities and should not be expanded.

These rules turn back the clock on women's health and access to care. As representatives of the Nation's women's health providers, we again respectfully request that the rules be withdrawn. Thank you.

Sincerely,

Hal C. Lawrence III, MD
Executive Vice President & CEO
American Congress of Obstetricians and Gynecologists

Kate McHugh, CNM, MSN, FACNM
Interim Chief Executive Officer
American College of Nurse-Midwives

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[i] Simmons, A et. al. The Affordable Care Act: Promoting Better Health for Women. Office of the Assistant Secretary for Planning and Evaluation Issue Brief. Department of Health and Human Services. June 14, 2016, available at https://aspe.hhs.gov/sites/default/files/pdf/205066/ACAWomenHealthIssueBrief.pdf .

[ii] Becker, N. V., & Polsky, D. (July 2015). Women Saw Large Decrease in Out-of-Pocket Spending for Contraceptives After ACA Mandate Removed Cost Sharing. Health Affairs, 34(7), pp. 1204-1211, available at http://content.healthaffairs.org/content/34/7/1204.abstract .

[iii] Ibid.

[iv] Finer, L.B., Zolna, M.R. Declines in Unintended Pregnancy in the United States, 2008-2011. N Engl J Med 2016; 374:843-52

[v] Secura GM, Madden T, McNicholas C, Mullersman J, Buckel CM, Zhao Q, et al. Provision of no-cost, long-acting contraception and teenage pregnancy [published erratum appears in N Engl J Med 2014;372:297]. N Engl J Med 2014;371:1316–23.

[vi] Mayer JP. Unintended childbearing, maternal beliefs, and delay of prenatal care. Birth. 1997;24(4):247-52.

[vii] Orr ST, Miller CA, James SA, et al. Unintended pregnancy and preterm birth. Paediatr Perinat Epidemiol. 2000;14(4):309-13.

[viii] Barber JS, Axinn WG, Thornton A. Unwanted childbearing, health, and mother-child relationships. J Health Soc Behav. 1999;40(3):231-57.

From:	Thornton, Jeanette
To:	Pate, Randy (CMS/CCIIO); Hammer, Christine E. (CMS/CCIIO); Wilkinson, Emily (HHS/IOS); Mayhew, James A. (CMS/CCIIO); Carver, Katherine J. (CMS/CCIIO); Clemmons, Cam L. (CMS/CCIIO); Mlawsky, David (CMS/CCIIO); Turner, Amy - EBSA; Rivers, Amber - EBSA; Kevin.Knopf@Ex (6) Kathryn.Johnson@Ex (6) Carol.Weiser@Ex (6) Brady, Will (HHS/IOS); Wilkinson, Emily (CMS/CCIIO)
CC:	Berry, Kate; Venkataraman, Rashi
Sent:	10/4/2017 5:54:51 PM
Subject:	Follow up from today's call RE Preventive Services
Attachments:	AHIP Feedback for Preventive Svcs_10.4.17.pdf

Thanks so much for the time today. Attached is additional detail on the recommendations we discussed.

Please let us know if you need anything further.

Jeanette

Jeanette Thornton | Senior Vice President, Product, Employer, and Commercial Policy
America's Health Insurance Plans

Ex (6)

Coverage of Preventive Services
AHIP Suggestions for Improvement for CCIIO
Follow-Up to October 4, 2017 Call

Overarching Theme
Translating evidence-based preventive services recommendations for clinical practice into sound public and private health benefit designs and coverage policies requires practical application of clinical options and appropriate medical management.

Background
Health insurance plans provide coverage for services recommended by the United States Preventive Services Task Force (USPSTF), Advisory Community on Immunization Practices (ACIP) Vaccine Recommendations, HRSA Women Preventive Services Initiative (WSPI) Guidelines, Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) Guidelines, and the American Academy of Pediatrics' Bright Futures Guidelines.

Recommendations About Process

- Reduce administrative burdens on plans by aligning timing of USPSTF recommendations and effective dates to once or twice a year rather than on a rolling basis. This alignment should extend to *all* recommendations/guidelines from ACIP, WSPI, ACHDNC, and Bright Futures (with coordinated release of recommendations in batches).
    a. Increase time for effective implementation – for example, effective date should be January 1, two years after issuance.

- USPSTF should incorporate additional considerations into its process
    - Seek input during public comment period on "What additional questions need to be answered to convert these recommendations into coverage policy?"
    - Collaborate with CCIIO (and other Tri-Agency partners) to provide guidance on coverage policy or benefit design as each USPSTF recommendation is released. This guidance should incorporate stakeholder feedback (e.g., AMA, AAP, AHIP).
    - Ensure consistency across different guidelines (e.g., USPSTF recommendation for cholesterol screening doesn't match the AAP Bright Futures Guideline).
    - Coding issues: Preventive services recommendations should not go into effect until there is a corresponding billing code.
        - Provider education is needed to reduce erroneous coding of preventive services as diagnostic (e.g., colonoscopies where a polyp is identified) which may lead to inappropriate imposing of cost-sharing on consumers.

- Improve transparency of the WSPI process for women's preventive guidelines
    - WSPI was tasked with developing preventive services guidelines that were *not* otherwise addressed by USPSTF recommendations. Some WSPI guidelines are duplicative of USPSTF (e.g., screening for cervical cancer, HIV screening, breastfeeding interventions). Recommend that redundancy is eliminated and there is a clear delineation of USPSTF recommendations vs. WSPI guidelines (e.g., USPSTF clearly defers to Bright Futures on certain recommendations).

  - WSPI's current process has strict limits on public comments (e.g., 1,000-character limit for comments on each guideline).

- Improve transparency of Tri-Agency (DOL/HHS/Treasury) FAQ process by gathering stakeholder input in advance of publishing FAQs and providing a reasonable *future* date for compliance and not making them retroactive.

- Consider expanding efforts aimed at educating consumers about their preventive service coverage (e.g., toolkits, patient-facing materials, etc.)

Recommendations About Substance of Guidelines and FAQs

- OTC items (e.g., aspirin to reduce myocardial infractions, folic acid supplements for pregnant women) should not be required to be covered without cost-sharing when prescribed by a health care provider (aspirin FAQ available here, question 4).
  - USPSTF recommendations and CMS FAQs have required plans to cover the use of OTC items. This current policy places an undue burden on plans to develop coverage policies for low cost items available without a prescription that have not traditionally been included as insurance benefits.

- Preserve health plans' flexibility to use reasonable medical management to promote value. Avoid prescriptive approaches or state-specific definitions. FAQs should not erode or restrict the important value of medical management in ensuring access and affordability (e.g., tobacco cessation)
  - Reasonable medical management is affirmatively recognized in regulation (75 CFR 41729). The preamble and the regulations explain that plans and issuers can use reasonable medical management techniques to determine coverage limitations if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment or setting for the provision of that service. Medical management tools help ensure patients receive the right care at the right time and offer individuals assistance in managing their own care and improve personal health outcomes and health status.
  - Medical management techniques will help facilitate the appropriate application of the recommendations and guidelines in real-life situations for the benefit of consumers.
  - For example, USPSTF describes seven FDA approved OTC and prescription medications for treating tobacco dependence. Studies have shown there is equal effectiveness among various smoking cessation methods (e.g., nicotine patch, varenicline, combination NRT, etc.).

- Promote value-based insurance design to allow plans to encourage people to use more efficient settings of care (e.g., charge copay for colonoscopy in hospital but not in ambulatory surgery center, charge copay for behavioral intervention for weight loss counseling for individual sessions but not for group sessions)

- Of note, some USPSTF recommendations target narrow populations of patients that would be covered based on risk and diagnosis. Identifying these patients can be a

significant challenge for plans because the necessary information needed to apply the benefit may not be routinely collected and documented.

- For example, the USPSTF statin recommendation states that plans should cover statins for adults aged 40-75 with no history of CVD, 1 or more CVD risk factors, and a calculated 10-year CVD event risk of 10% or greater. However, prescription claims data does not include information about diagnosis, risk factors for CVD, or the 10-year risk score.

Expanding the Preventive Care Safe Harbor for HDHPs

High Deductible Health Plans (HDHPs), in order to be eligible to be paired with a Health Savings Account (HSA), must meet certain criteria as established by Section 223(c) of the federal Internal Revenue Code. Generally, HDHPs may not provide benefits for any year until the minimum deductible for that year has been satisfied. The Code, however, has an exception for certain preventive care services. Under this exception, often referred to as the preventive care safe harbor, HDHPs may voluntarily provide coverage for preventive services prior to the deductible being met.

We recommend that Treasury amend guidance that limits the definition of preventive services. An expanded definition would encompass preventive treatments for chronic health conditions. The goal of this expanded definition for the safe harbor would be to allow greater adoption of VBID among HDHPs.

We have shared the following recommendation with Treasury:

> ***Updates to existing IRS Notices 2004-23 and 2004-50:***
> Preventive care for purposes of Code section 223(c)(2)(C), and the Internal Revenue Service's preventive care safe harbor thereunder, includes chronic disease prevention. For these purposes, chronic disease prevention means the treatment or mitigation of a medical condition that is expected to last a year or more, requires ongoing medical attention, and limits one or more activities of daily living.
>
> To qualify for the preventive care safe harbor, payments made for chronic disease prevention by a high deductible health plan without a deductible or with a deductible below the minimum annual deductible may not exceed an actuarial value of [X] per plan year [alternative: may not increase the plan's actuarial value by more than X per plan year]. The actuarial value of such payments made for chronic disease prevention shall be calculated by an actuary certified by the American Academy of Actuaries using generally accepted actuarial standards, and shall not take into account the value of any Health Savings Account associated with the high deductible health plan.